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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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STITES & HARBISON PLLC
1199 NORTH FAIRFAX STREET
SUITE 900
ALEXANDRIA, VA 22314

EXAMINER	
NATNITHITHADHA, NAVIN	
ART UNIT	PAPER NUMBER
3735	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/682,372	OLLMAR ET AL.	
	Examiner	Art Unit	
	NAVIN NATNITHITHADHA	3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 February 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17 and 19-43* is/are pending in the application.

4a) Of the above claim(s) *1-13* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *14-17 and 19-43* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *20 August 2007* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

1. Applicant's arguments, see Remarks, pp. 2-6, filed 05 February 2008, with respect to the rejection of claims 14-17 and 19-43 under 35 U.S.C. 103(a) as being unpatentable over Davies et al, U.S. Patent No. 6,922,586 B2 ("Davies") in view of Sieburg et al, U.S. Patent No. 7,103,398 B2 ("Sieburg"), have been fully considered, but they are not persuasive.

Applicant contends, see Remarks, pp. 2-3, the following as to how Davies is distinguishable from Applicant's disclosed invention:

> …if the system according to Davies is applied to the skin of the subject, even if the penetration depth can be adjusted by spaced electrodes, so that the current may reach the skin layer beneath the stratum corneum where the most valuable information about the skin condition can be obtained, the current must still pass through the stratum corneum. It is known though that α-dispersion from the stratum corneum is broad and large and may overshadow impedance data obtained from the skin underneath. As such, the use of the Davies system and method would dilute the results obtained and the diagnosis of the skin condition would therefore be unspecific and not useful.
>
> …unlike the present invention, when applying the Davies method one must first know whether the examined tissue is abnormal or not before the measurement is made. As such, Davies actually teaches away from the present invention, which discloses a method where high accuracy diagnosis is achieved without applying any agent and without a need of previous knowledge about the tissue condition.
>
> …while Davies also indicates that electrodes penetrating the stratum corneum might be used (column 10, line 58), the reference teaches that this would only be done to decrease impedance and not, as the present invention teaches, to avoid the dispersions caused by the stratum corneum.

In regards to Sieburg, Applicant contends, see Remarks, pp. 4-5, the following:

> Accordingly, measurements performed according to Sieburg, where needle or needle-like electrodes sense a signal separately, will result in high measurement uncertainty originating from a natural variation of skin impedance and may lead to a false diagnosis and depth profile. As such, Sieburg also teaches away from the present invention wherein this problem is avoided in that the spikes are not individually addressed but each electrode contains a plurality of spikes thereby measuring over a large area. The Sieburg reference thus cannot be added to the Davies reference to disclose or make obvious Applicants' claimed invention.

However, these arguments are not persuasive.

Applicant's arguments fail to comply with 37 CFR 1.111(b) because they amount to a general allegation that the claims define a patentable invention without specifically pointing out how the language of the claims patentably distinguishes them from the references.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Also, Applicant states advantages of these features over Davies and Sieburg, but did not cite any evidence to support these allegations.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. Claims 14-17 and 19-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Davies in view of Sieburg.

Claims 14-17 and 19-29: As to claims 14-16, 19-21, and 27-29, Davies teaches a method for diagnosing a diseased condition of the skin (see Abstract and figs. 1-4), the method comprising the steps of:

(i) placing an electrical conducting probe ("prove device") 105/400 against a skin surface of the subject (see fig. 4A), wherein the probe 105/400 comprises a plurality of electrodes (see fig. 3), wherein a first electrode ("current passing electrodes") 5 and a second electrode (first ring of "voltage sensing electrodes") 8 of the plurality of electrodes are spaced a first distance from each other and wherein the first electrode 5 and a third electrode (second, inner ring of "voltage sensing electrodes") 8 of said plurality of electrodes are spaced a second distance from each other;

(ii) passing an electrical current through the electrodes to obtain a value of skin impedance, wherein said electrical current is separately passed between the first electrode 5 and the second electrode (first ring of "voltage sensing electrodes") 8 and between the first electrode 5 and the third electrode (second, inner ring of "voltage sensing electrodes") 88 to obtain at least a first value of impedance and at least a

second value of impedance (see fig. 3 and col. 11, ll. 36-44, and col. 11, l. 64, to col. 12, l. 12); and

(iii) using reference data to determine whether the impedance value indicates the diseased condition, such as skin cancer (see col. 8, ll. 60-65, col. 9, ll. 48-65, col. 9, l. 66, to col. 10, l. 19, and col. 11, ll. 1-4).

Davies does not teach "each electrode furnished with a number of spikes, the spikes being laterally spaced apart from each other and being of sufficient length to penetrate the stratum corneum" in claim 1, along with the subject matter of claims claims 17 and 22-26, which directed to the amount and dimensions of the spikes. However, Sieburg teaches a method for "electrical signal sensor and/or signal application" (see Abstract and figs. 1-8), comprising: electrodes 16 furnished with a number of spikes 34 having a variety of dimensions (see para. [0059], [0061], and [0063]). Therefore, it would have been obvious for one of ordinary skill in the art at the time the invention was made to modify Davies's electrode structure with Sieburg because Sieburg discloses the following passage directed to the advantage of including need-like electrode configurations to the type of electrical sensing/application to human or animal tissue (see para. [0026]):

> Arrays of needles or needle-like configurations are of primary interest for the medical diagnosis and therapy of the skin or other organs and tissues of humans and animals. Such an array of electrodes, however, might also be useful for other configurations whenever it is possible to establish electrical contact with the component to be investigated and when the determination of an impedance or electrical image provides meaningful information. This typically applies to components which do not have a hard outer surface because in this case only individual electrodes would establish an electrical contact. Therefore, components of interest are typically softer on their surface like elastomeric and similar components.

In fact, a particular area of interest in medical diagnosis disclosed by Seiburg is te diagnosis of cancer (see Seiburg, para. [0005]). Furthermore, Davies discloses that "[t]he system 100 interfaces with a probe device 105 including multiple electrodes, wherein the actual implementation of the probe device 105 depends on the organ and condition under test" (see Davies, col. 10, ll. 60-66), and thus, suggests that other multiple electrode configurations can be used depending on the tissue under testing, such as the invention disclosed by Sieburg.

Claims 30-43: Because Applicant stated that the added new apparatus claims 30-43 correspond to method claims 14-17, 19-27, and 29, respectively, and are not independent and distinct inventions, the claims 30-43 are rejected for the same reasons as stated above for claims 14-17, 19-27, and 29.

Conclusion

3. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to NAVIN NATNITHITHADHA whose telephone number is (571)272-4732. The examiner can normally be reached on Monday-Friday, 9:00 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on (571) 272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Charles A. Marmor, II/
Supervisory Patent Examiner
Art Unit 3735

/N. N./
Patent Examiner, Art Unit 3735
04/18/2008